federal register

WEDNESDAY, JANUARY 24, 1973
WASHINGTON, D.C.

Volume 38 ■ Number 16

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Manufacture and Processing

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 128b—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

A notice of a petition filed by the National Canners Association (NCA), 1133 20th Street NW., Washington, DC 20036, on the commercial processing of foods in hermetically sealed containers was published in the FEDERAL REGISTER of November 12, 1971 (36 FR 21688). The petition proposed that there be promulgated in Part 3 of this chapter a statement of policy regarding the application of emergency permit provisions of section 404 of the Federal Food, Drug, and Cosmetic Act to the commercial processing of foods for human consumption manufactured, processed, or packed in hermetically sealed containers which are processed by heat either before or after being sealed in the containers.

This petition, accompanied by an index and appendix, was published as received and was regarded by the Commissioner of Food and Drugs as a regulation proposal, with the usual opportunity for interested persons to submit written comments within 60 days. In response to the notice, 30 comments were received from members of industry, trade associations, and a law school. In addition, the petitioner submitted revisions of the proposal which incorporated comments it had received directly from respondents or that were filed with the Hearing Clerk.

On November 14, 1972, a notice was published in the FEDERAL REGISTER (37 FR 24117) that a tentative final order, containing minimum good manufacturing regulations for thermally processed low-acid foods packaged in hermetically sealed containers, had been prepared and had been placed on display in the Hearing Clerk's office for a period of 20 days beginning November 15, 1972, and ending on December 4, 1972. Any persons who wished to submit further comment or to meet with Food and Drug Administration officials to discuss the tentative final order were invited to do so within the 20 days. In response to this notice, 14 comments were received from eight members of industry, three trade associations, one State, one university, and one Member of Congress.

After consideration of all of the comments, the revisions submitted by the petitioner, and further discussions with the petitioner, the Commissioner concludes that the complexities of regulations governing application of section 404 of the Federal Food, Drug, and Cosmetic Act, as proposed by the petitioner, require further study. Such regulations, including both the registration and record inspection provisions proposed by NCA and general procedural regulations with respect to the use of section 404, are presently being developed in order to establish an adequate enforcement mechanism. In the meanwhile, regulations are needed to specify good manufacturing practices to be followed in the manufacture, processing, or packing of thermally processed low-acid foods packaged in hermetically sealed containers. It is important that these substantive requirements be promulgated as soon as possible, and that they not be delayed pending development of the procedural and enforcement provisions. The Commissioner therefore concludes that the appendix to the statement of policy proposed by NCA, together with the comments received regarding the appendix, with modifications which the Commissioner deems to be necessary, should be promulgated as minimum good manufacturing practices regulations for thermally processed low-acid foods packaged in hermetically sealed containers.

The comments received and the Commissioner's conclusions are as follows:

Several comments were received regarding the definition of low-acid foods. One trade association suggested changing the definition to include products with a pH of 4.5 or greater. One manufacturer recommended that, inasmuch as the pH value of a low-acid food must be an arbitrary selection of some pH value below 7, the definition be set at a level greater than the proposed 4.6 for 1 or 2 years after the effective date of the regulations in order to allow processors time to comply with the regulations. The selection of a pH value of "greater than 4.6" in the definition is based on available scientific information as to the conditions under which microorganisms of public health significance can grow and/or produce toxins. The value allows for the safety factor which is deemed adequate and necessary to protect the public health. The Commissioner fails to see how the selection of a pH value above that proposed for 1 or 2 years is in the interest of public health nor does he believe that a pH value of 4.5 as the maximum is necessary. The Commissioner has rejected the suggestion of another trade association that allowances be made in the definition of low-acid foods, or elsewhere, for the normal variations of results obtained using commercial pH meters; it is the function of the commercial processor to ensure that such instruments are operating accurately. One manufacturer recommended a change in that part of the proposed definition relating to "any food in which for the purpose of processing the pH value is reduced by acidification." He suggested that "food" be further defined as a "normally low-acid fruit or vegetable." The Commissioner has accepted this recommendation, has elaborated upon it, and, accordingly, has revised the definition of low-acid foods.

Seven comments recommended exclusion from coverage under the regulation, as finally adopted, of food products which, because of a low-water activity or high-sugar content, do not contain sufficient moisture to support the growth of pathogens. The Commissioner finds that it was not the intent of the proposal to include such products. The definition of "low-acid foods" has been rewritten specifically to exclude those products with a moisture content as expressed by a water activity of 0.85 or less, which is deemed insufficient to allow the growth of pathogens.

Five comments recommended that foods to which heat is applied primarily for some purpose other than to achieve commercial sterility, such as pasteurization, flavor development, or removal of moisture, be excluded from coverage under the regulations. The Commissioner finds that it was not the intent of the proposal to include such foods. Such foods will not be subject to coverage under the good manufacturing practices regulations set forth below.

One trade association requested that the application of the tentative final order to the pet food industry be suspended until the association and members of the industry have an opportunity to carefully study and review the proposed regulations and offer formal comments to the Food and Drug Administration. The original proposal did not exempt the pet food industry, and the Commissioner, as well as others with interest in this matter, had always considered that the regulation should apply to that segment of the canning industry and affirms that fact. In the event that evidence should later demonstrate that there is no need to apply the subject regulation to canned pet foods, the Commissioner will consider any such evidence brought to his attention.

Three persons commented regarding the definition of hermetically sealed container. One of these persons wished to clarify the fact that plastic containers may be used for packaging. The Commissioner has determined that the intent of the definition in the proposal was to define the container's function, not to define the material of which the container is to be constructed. The definition has been revised to clarify the function of a hermetically sealed container; however, it does not specify the material of which the container is to be constructed. Any material which otherwise fulfills all of the requirements of the Federal Food, Drug, and Cosmetic Act may be used in the construction of the container.

Two comments were received regarding the definition in the proposal of "commercial sterility". One trade association stated that at least 1 year of additional study would be needed to determine whether the new definition of commercial sterility would result in prolonged processing which would affect the nutritional quality of foods. One manufacturer recommended that the definition not include the requirement that foods be free of viable forms of more heat resistant micro-organisms of nonhealth significance capable of reproducing under normal conditions of storage and distribution. The Commissioner has determined that the definition of commercial sterility in the proposal is not a "new" definition and that it is generally accepted as a re-

quired condition for low-acid foods in hermetically sealed containers. The definition of commercial sterility as set forth below further defines "normal conditions of storage and distribution" as "normal nonrefrigerated conditions of storage and distribution".

One trade association and one manufacturer recommended that the specification "1 inch or larger" be deleted from the definition of "vents" because it is excessively detailed and restrictive to the point of limiting engineering solutions which properly should take into consideration the construction and layout of the particular establishment. The specification "1 inch or larger" has been deleted from the definition of "vents" as set forth below.

Ten persons commented on the proposed requirements regarding container coding. Their principal objection was to the requirement that the packing period code be changed every 4 hours or less. The suggestion was made that the change be based on the number of containers processed. The regulation set forth below has been revised to require that the packing period code be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Although this regulation does not specify the time interval for changing the packing period code, such time intervals are suggested. One manufacturer requested that the code on glass containers not be required to include product identification. The Commissioner, after consideration of this comment and other available information, concludes that the purpose of requiring the container code is to identify a lot of product throughout its history of processing, sale, and distribution. The requirement that the container code specify the product contained therein is not solely to aid in the identification of the contents of the container but also to allow for the identification of production and processing records which relate to a specific lot of product. The inclusion in the code of the identity of the product is essential in order to differentiate between processing records of different products processed at the same plant, on the same date, and during the same packing period. The regulation as set forth below retains the provision that the container code include the identity of the product contained therein. One trade association suggested that provisions be made to allow a processor to add additional information in the code as, for example, the line on which production took place. The proposal required that the container code provide information regarding the establishment where packed, the product contained therein, the year packed, the day packed, and the period of the day packed. The Commissioner finds that the container coding requirements, as proposed, do not prevent the processor from including any other information in the code which he deems necessary.

One trade association opposed the proposed requirements regarding processing and production records. While agreeing to the need to maintain and keep such records, this trade association took exception to several of the requirements as being excessive, unwarranted, and unnecessary. The Commissioner finds that the recordkeeping requirements as set forth in the proposal and in the regulation below are necessary to permit a determination from the records of whether the thermal processing was sufficient to achieve commercial sterility of the product or to destroy micro-organisms of public health significance.

One trade association objected to the requirement that permanent records be kept of the development of the processes used. This comment is rejected because the Commissioner is of the opinion that the establishment of a process and the proof that the process is safe are essential in the assurance that the food processed is commercially sterile.

Two comments were received regarding the proposed requirements for the examination of container closures and the recording of observations of such examinations. It was suggested that the intervals required for visual examination of container closures and for teardown examination of can seams be based not on time but on the number of containers moving through the closing machine. This portion has been revised to delete the proposed requirement that such container closure examinations be done at specified time intervals, although certain time intervals are recommended. The opposition to the recording of observations is rejected on the basis that the keeping of such records is an accepted good manufacturing practice.

Ten persons commented on the proposed requirement that the retort room operations and the container closure inspections be performed under the "direct personal supervision" of a supervisor or manager who has attended an approved course of instruction in retort operations or container closure inspection. The recommendation that the words "direct personal" be deleted has been accepted and the regulation as set forth below requires that operators of retorts, processing systems, and aseptic packaging systems, and container closure inspectors be under the "operating supervision" of a person who has attended a school approved by the Commissioner. The Commissioner states that it is the intent of this requirement for a person or persons who has (have) attended a school approved by the Commissioner and who has (have) been identified by that school as having satisfactorily completed the prescribed courses of instruction to be on duty at the plant whenever low-acid foods are being thermally processed and/or packaged in hermetically sealed containers. One manufacturer suggested that such supervisors be identified on the basis of experience alone without school attendance. The Commissioner has concluded that the only way to ensure that all such supervisors receive the information regarding operations of retorts, processing systems, and aseptic packaging systems, and container closure inspection which is deemed necessary for proper thermal processing and packaging operations is to require all such supervisors to attend a school approved by him and to be identified by the school as having satisfactorily completed the prescribed courses of instruction. The Commissioner, after consideration of all available information, concludes that 20 months should be sufficient time for processors to ensure that their personnel receive this required training. The provisions of § 128b.10 regarding training of personnel shall become effective 20 months after the publication date of this order.

Two trade associations and one manufacturer opposed the proposed requirement that processes and venting procedures be posted in a conspicuous place near the retorts. They recommended that provisions be made for posting such information in such a way that information regarded as trade secrets would not be revealed. The Commissioner agrees and this requirement has been revised to allow the processor to either post the scheduled processes and venting procedures near the processing equipment or make them readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration.

One trade association and one manufacturer took exception to the proposed mandatory requirement that some of the containers on the top of retort baskets, trucks, cars, or crates containing unretorted material be plainly and conspicuously marked with a heat sensitive indicator. The trade association recommended that this requirement be a suggested and optional method of evidencing proper processing. One distributor, one manufacturer of marking inks, and one Member of Congress suggested that each individual food container be marked with a heat sensitive indicator as a means of determining whether or not the containers have been thermally processed. The Commissioner has concluded that the color change of a heat sensitive indicator were applied to each individual food container does not insure that the container has received a thermal process sufficient to render its contents commercially sterile. The Commissioner further concludes that, since such heat sensitive indicators can serve as a visual means of determining if the containers have been retorted, each retort basket, truck, car, or crate containing unretorted materials or some of the containers therein shall be marked with a heat sensitive indicator as stated in the proposal.

One comment was received which recommended deleting the proposed requirement that timing devices be easily read to the nearest minute, on the basis that such a timing device would be totally inadequate for short-time, high-temperature processes. The petitioner, in a revision of the proposal, recommended that pocket or wrist watches not be considered satisfactory for timing purposes. The Commissioner agrees with both of these comments and the section in the regulation regarding timing devices has been revised to reflect these recommendations.

Two comments recommended that provisions be made for the use of temperature indicating devices other than mercury-in-glass thermometers. The Commissioner has determined that the mercury-in-glass thermometer is the recognized standard against which all other temperature indicating devices are checked and calibrated. The regulation as set forth below retains the requirement that all retorts be equipped with mercury-in-glass indicating thermometers. However, because of the speed of the thermal process, alternate temperature indicating devices such as thermocouples will be allowed in aseptic processing and packaging systems. This change is reflected in the regulation as set forth below.

One trade association recommended that the words "and maintains" be deleted from the definition of "coming-up-time". The Commissioner agrees and the definition has been so revised.

Two processors commented that the requirement regarding the temperature sensitivity of a temperature recording device was impractical because it exceeds the capability of any practical available device on the market and is unnecessary in view of the requirements contained elsewhere in the regulations. The Commissioner accepts their recommendation and this requirement has been deleted from the regulation.

One trade association and one manufacturer recommended deletion of the proposed requirement that indicating thermometers be installed "where they are illuminated". They stated in their comments that they wanted to eliminate the possibility of having to install some special illumination for the thermometer only. The Commissioner accepts their recommendation and the regulation has been so revised to state that "Thermometers shall be installed where they can be accurately and easily read".

One trade association and one manufacturer submitted comments concerning recording thermometers. One comment made recommendations concerning the size of the recording chart working scale. The other comment recommended that the recording thermometer be adjusted to "substantially read in agreement" with the mercury-in-glass thermometer. After consideration of these comments and other relevant information, the Commissioner has concluded that those parts of the proposal concerning recording thermometers be revised to state that recording thermometer charts shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature and that the temperature recording device for each retort shall be adjusted to agree within 1° F. of the mercury-in-glass thermometer. One person asked whether recorders with two or more pens would satisfy the requirement that there be a temperature recording device for each retort. The Commissioner will allow the use of a multirecording device for more than one retort, provided that each retort record be separate on the chart so that it can be identified.

The Commissioner, after consideration of all available information, has concluded that 90 days should be sufficient time for processors to install recording thermometers on thermal processing equipment. Those provisions of § 128b.6 regarding the installation of recording thermometers on thermal processing equipment shall become effective 150 days after the publication date of this order.

Two comments suggested that pressure gages be made mandatory on all retorts. The Commissioner agrees and those parts of the proposal regarding pressure gages have been revised to make mandatory the equipping of each retort with a pressure gage. One trade association made additional comments recommending certain mandatory requirements for pressure gages regarding scale graduations, testing, and installation on the retorts. The Commissioner has concluded that the recommendations of the trade association are to be included in those parts of the regulation concerning pressure gages; however, the recommendations regarding scale graduations, testing, and means of installation on the retort are not made mandatory requirements.

One trade association commented on that part of the proposal dealing with the steam inlet in still retorts. This trade association recommended that the clause "for proper venting" be changed to read "for proper heating and venting". This recommendation has been accepted in part and the clause has been revised to read "for proper operation of the retort". In response to this trade association's recommendation concerning the wording describing the relative positions of the steam inlet and the vents, the sentence to which they referred has been revised to read "steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion."

One trade association commented that the proposal is in error in that it requires a bottom bleeder in still retorts for pressure processing in steam only where there is top steam inlet and bottom venting. The association recommended that a bottom bleeder be made mandatory on all still retorts (except when processing in water) to take care of condensate and/or water leakage. This recommendation has not been accepted. The Commissioner has concluded that, because of the design and operation of retorts, condensate or water leakage presents no processing problem if steam is introduced into the bottom of the retort and the retort is vented at the top.

One trade association commented extensively on the detailed descriptions in the proposal regarding the venting of still retorts for processing in steam. This trade association commented that the detailed venting procedures mean little or nothing without proper consideration of the size of the steam inlet, the available steam supply and pressure thereof, the size of the retort, and the load within the retort. The Commissioner agrees that these factors affect retort venting. However, the proposal clearly states that the detailed venting procedures are for some typical installations and operating procedures and that other installations and operating procedures may be adequate to ensure proper retort venting. It is the responsibility of each processor to determine that the venting procedures he follows are adequate to ensure removal of air from the retorts before timing of the scheduled process is started.

One manufacturer questioned the need for a pressure recording device on retorts for pressure processing in water. The proposal has been revised to reflect this comment. Pressure recording devices will not be required; however, the regulation as set forth below recommends that retorts for pressure processing in water be equipped with an adjustable relief, or control, valve in the overflow line and requires an automatic pressure controller on the air supply.

Two manufacturers recommended deletion of the requirement for a water level indicator in retorts for pressure processing in water. This recommendation has not been accepted; a means of determining the water level in the retort is essential to ensure that all containers are covered by water during the entire coming-up-time and processing periods. One manufacturer objected to the requirement that approximately 6 in. of water cover the top layer of glass jars during the entire coming-up-time, processing, and cooling periods. The proposal has been revised to reflect this comment and now states that water shall cover the top layer of containers during the entire coming-up-time and processing periods and should cover the top layer of containers during the cooling periods. This same manufacturer recommended a change in the mandatory requirement in the proposal concerning retort headspace and also commented on that part of the proposal regarding the introduction of container cooling water. The proposal has been revised to delete any mandatory requirements regarding retort headspace. The method of introducing cooling water as stated in the proposal was not a mandatory requirement; however, the regulation retains recommendations as to how the cooling water should be introduced.

One trade association and one manufacturer commented regarding the method of determining minimum headspace in containers of homogeneous liquids. The proposal has been revised and the regulation as set forth below allows for the measurement of minimum headspace in solder-tipped, lap seam (vent hole) cans by net weight determination.

At the recommendation of the petitioner and others, new subparagraphs regarding "Emergency stops" and "Temperature drop" have been added to the part of the regulation concerning continuous agitating retorts in order to specify what is to be done to ensure safe processing in the case of a retort jam, breakdown or temperature drop.

One manufacturer commented that "it would appear that less than six temperature recorders should be adequate to assure satisfactory processing records from a hydrostatic cooker, especially when no more than one is required on all other types of cookers." The proposed regulation has been revised and the regulation as set forth below requires that each hydrostatic retort be equipped with a temperature recorder in the steam chamber and additional recorders near the top and bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the water legs.

Seven comments were submitted concerning the proposed requirements for aseptic canning systems. These comments concerned timing devices, means of calculating the holding tube length, temperature sensing and recording devices, flow rates, flow diversion valves, and resterilization. This part of the proposal has been rewritten in its entirety and the comments received are reflected in the regulation as set forth below.

One comment suggested that the scientific methods used to determine the adequacy of new systems for processing low-acid foods shall include the use of system resistant organisms to inoculate both the product and the system. The regulation as set forth below includes a requirement that acceptable scientific methods be used in establishing heat sterilization processes (including such processes for new systems). Acceptable scientific methods include the use of system resistant organisms to inoculate the product or system, as applicable.

That part of the proposal concerning container cooling has been revised to reflect three comments received regarding chemical or physical treatment of cooling water by means other than chlorination. In response to two comments, those provisions in the proposal regarding the cooling of containers to specified temperatures have been deleted.

All other comments have been carefully considered by the Commissioner and, where deemed to be appropriate, have been incorporated into the regulation as set forth below.

As noted elsewhere in this document, the Commissioner has concluded that the appendix to the statement of policy proposed by the petitioner together with the comments received regarding the appendix shall form the basis for good manufacturing practices regulations for thermally processed low-acid foods packaged in hermetically sealed containers. In addition to revising the proposal to reflect the comments received, the Commissioner has added to, deleted, and rearranged parts of the proposal as he deemed to be necessary for the implementation of the proposed regulation.

Accordingly, having evaluated the comments received and other relevant material, the Commissioner concludes that the regulation should be promulgated as set forth below.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), Chapter I of the Title 21 is amended by adding a new part 128b as follows:

Sec.
128b.1 Definitions.
128b.2 Current good manufacturing practice.
128b.3 Product preparation.
128b.4 Establishing scheduled processes.
128b.5 Operations in the thermal processing room.
128b.6 Equipment and procedures.
128b.7 Containers.
128b.8 Processing and production records.
128b.9 Deviations in processing.
128b.10 Personnel.

AUTHORITY: Sec. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a).

§ 128b.1 Definitions.

(a) "Aseptic processing and packaging" means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of micro-organisms.

(b) "Bleeders" means openings used to remove air, that enters with steam, from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) "Coming-up-time" means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) "Commercial processor" shall include any person engaged in commercial, custom, and so-called sportsman processing or institutional (church, school, penal, or other organization) processing of food.

(e) "Commercial sterility" of food means the condition achieved by application of heat which renders such food free of viable forms of micro-organisms having public health significance, as well as any micro-organisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment which renders such equipment and containers free of viable forms of micro-organisms having public health significance as well as any micro-organisms of nonhealth significance capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) "Flame sterilizer" means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, over gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(g) "Headspace, gross" is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(h) "Headspace, net" of a container having a double seam, such as a can, is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(i) "Hermetically sealed container" means a container which is designed and intended to be secure against the entry of micro-organisms and to maintain the commercial sterility of its contents after processing.

(j) "Incubation" means the holding of a sample(s) at a specified temperature for a specified period of time before examination.

(k) "Initial temperature" means the average temperature of the contents of the coldest container to be processed at the time the sterilizing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(l) "Lot" means the product produced during a period of time indicated by a specific code.

(m) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH value greater than 4.6 and a water activity greater than 0.85 and also includes any normally low-acid fruits, vegetables, or vegetable products in which for the purpose of thermal processing the pH value is reduced by acidification. Tomatoes, pears, and pineapples, or the juices thereof, having a pH of less than 4.7 and figs having a pH of 4.9 or below shall not be classed as low-acid foods.

(n) "Minimum thermal process" means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of micro-organisms of public health significance.

(o) "Retort" means any closed vessel or other equipment used for the thermal processing of foods.

(p) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of micro-organisms of public health significance.

(q) "Shall" and "should." As used in this part, "shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(r) "Vents" means openings controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(s) "Water activity" or "a_w" means the vapor pressure of the food product divided by the vapor pressure of pure water

under identical conditions of pressure and temperature.

§ 128b.2 Current good manufacturing practice.

The criteria in §§ 128b.3 through 128b.10 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 128b.3 Product preparation.

(a) Incoming raw materials, ingredients, and packaging components should be inspected upon receipt to ensure that they are suitable for processing. Raw materials should be received in an area separate from the processing areas. Prior to being placed in inventory, ingredients susceptible to microbiological contamination which would render them unsuitable for processing either should be examined for microbiological condition or should be received under a supplier's guarantee that they are of a microbiological condition suitable for use in processing low-acid foods. Products should be held prior to processing in such a manner as to minimize growth of micro-organisms.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. Where the blanched food product is washed prior to filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. This may be done by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When normally low-acid fruits, vegetables, or vegetable products require sufficient acidification to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process.

§ 128b.4 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors which may affect the scheduled process (e.g., minimum headspace, consistency, maximum drained weight, etc.), shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, where necessary, but not be limited to microbial thermal death time data, process calculations based on product heat penetration data, inoculated packs, and incubation tests. Product heat penetration data may be mathematically converted in calculating processes for different container sizes and thermal processing temperatures. If incubation tests are necessary, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for establishing scheduled processes should include the containers from the test trials and a number of containers from each of four or more actual commercial production runs. The number of containers from actual commercial production runs should be determined on the basis of recognized scientific methods to be of a size sufficient to ensure the adequacy of the process. Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the person or organization making the determination.

§ 128b.5 Operations in the thermal processing room.

(a) Scheduled processes and venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or shall be made readily available to the retort or processing system operator and any duly authorized employee of the Food and Drug Administration.

(b) All retort baskets, trucks, cars, or crates containing unretorted food product, or some of the containers on the top of each basket, shall be plainly and conspicuously marked with a heat sensitive indicator, or by other effective means, which will visually indicate to thermal processing personnel whether or not each such unit has been retorted.

(c) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process.

(d) Timing devices used in recording thermal process time information shall be accurate to the extent needed to ensure that the processing time specified in the scheduled process is achieved. Pocket or wrist watches shall not be considered satisfactory for timing purposes.

(e) For continuous agitating retorts, the condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. A record shall be kept to show how it is functioning.

§ 128b.6 Equipment and procedures.

(a) *Equipment and procedures for pressure processing in steam in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer with a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to insure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a one-sixteenth inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F. from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort adjusted to agree within 1° F. of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a one-sixteenth inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with a steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Steam inlet.* The steam inlet to each still retort shall be large enough

to provide sufficient steam for proper operation of the retort. Steam may enter either the top portion or the bottom portion of the retort but, in any case, shall enter the portion of the retort opposite the vent; for example, steam inlet in bottom portion and vent in top portion.

(6) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of still retorts.

(7) *Steam spreaders.* Steam spreaders, which are perforated or other style continuations of the steam line inside the retort, should not be larger than the steam inlet line.

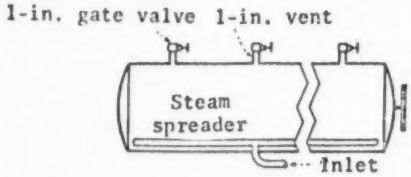
Horizontal still retorts shall be equipped with steam spreaders that extend along the bottom for the length of the retort; the perforations should be along the top 90° of this pipe. Horizontal still retorts over 30 feet long should have two steam inlets connected to the spreader. In vertical still retorts the steam spreaders, if used, should be in the form of a cross with the perforations along the top or sides of the pipe. The number of perforations in spreaders for both horizontal and vertical still retorts should be such that the total cross-sectional area of the perforations is equal to 1½ to 2 times the cross-sectional area of the steam inlet line.

(8) *Bleeders.* Bleeders, except those for thermometer wells, shall be one-eighth inch or larger and shall be wide open during the entire process, including the coming-up-time. For horizontal retorts, bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top. Vertical retorts shall have at least one bleeder opening located in that portion of the retort opposite the steam inlet. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to insure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(9) *Stacking equipment and position of containers.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is made of scrap iron, adequately perfo- should be approximately the equivalent of 1-inch holes on 2-inch centers. If dividers are used between the layers of containers, they should be perforated as above. When there is stratification of the product in the containers, the containers should be processed in such a position that the plane of stratification is vertical.

(10) *Vents.* Vents shall be installed in such a way that air is removed from the retort before timing of the process is started. Vents shall be controlled by gate, plug cock, or other adequate type valves which shall be fully open to permit rapid discharge of air from the retort during the venting period. Vents shall not be connected directly to a closed drain system. If the overflow is used as a vent, there shall be an atmospheric break in the line before it connects to a closed drain. The vent shall be located in that portion of the retort opposite the steam inlet; for example, steam inlet in bottom portion and vent in top portion. Where a retort manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, plug cock, or other adequate type valve. The retort manifold shall be of a size such that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The discharge shall not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Timing of the process shall not begin until the retort has been properly vented and the processing temperature has been reached. Retorts using air for pressure cooling shall be equipped with a ball or globe valve or suitable valve and piping arrangement on the air line to prevent air leakage into the retort during processing. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given in paragraphs (a)(10)(i) (*a*) through (*d*) and (ii) (*a*) and (*b*) of this section. Other installations and operating procedures which deviate from the above specifications may be used, provided that there is evidence that they accomplish adequate venting of air.

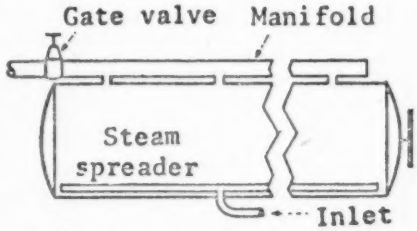
(i) *Venting horizontal retorts.* (*a*) Venting through multiple 1-inch vents discharging directly to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 2½ feet from ends of retort.

Venting method. Vent valves should be wide open for at least 5 minutes and to at least 225° F., or at least 7 minutes and to at least 220° F.

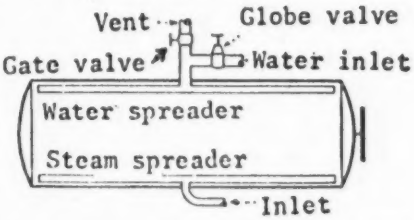
(*b*) Venting through multiple 1-inch vents discharging through a manifold to atmosphere.



Specifications. One 1-inch vent for every 5 feet of retort length; end vents not over 2½ feet from ends of retort; size of manifold—for retorts less than 15 feet in length, 2½ inches; for retorts 15 feet and over in length, 3 inches.

Venting method. Manifold vent gate or plug cock valve should be wide open for at least 6 minutes and to at least 225° F., or for at least 8 minutes and to at least 220° F.

(*c*) Venting through water spreaders.

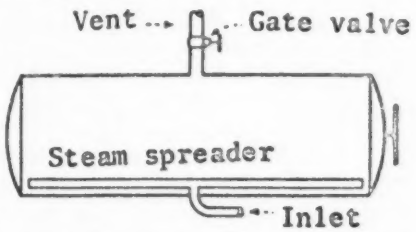


Size of water inlet, vent pipe, and vent valve. For retorts less than 15 feet in length, 2 inches; for retorts 15 feet and over in length, 2½ inches.

Size of water spreader. For retorts less than 15 feet in length, 1½ inches; for retorts 15 feet and over in length, 2 inches.

Venting method. Water spreader vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 225° F., or for at least 7 minutes and to at least 220° F.

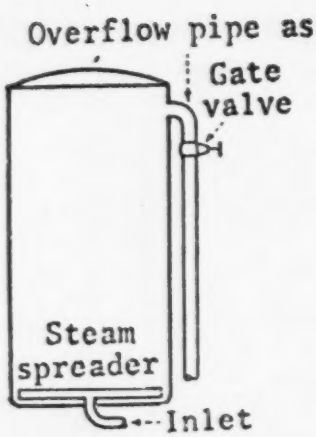
(*d*) Venting through a single 2½-inch top vent (for retorts not exceeding 15 feet in length).



Specifications: A 2½-inch vent equipped with a 2½-inch gate or plug cock valve and located within 2 feet of the center of the retort.

Venting method: Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 220° F.

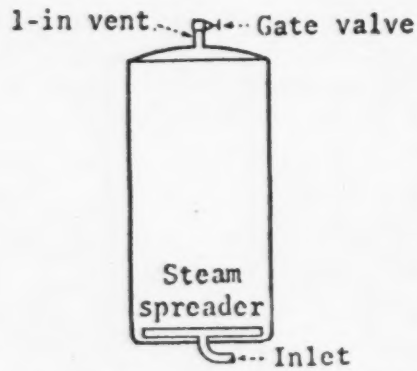
(ii) *Venting vertical retorts.* (*a*) Venting through a 1½-inch overflow.



Specifications. A 1½-inch overflow pipe equipped with a 1½-inch gate or plug cock valve and with not more than 6 feet of 1½-inch pipe beyond the valve before break to the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 4 minutes and to at least 218° F., or for at least 5 minutes and to at least 215° F.

(b) Venting through a single 1-inch side or top vent.



Specifications. A 1-inch vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere or to a manifold header.

Venting method. Vent gate or plug cock valve should be wide open for at least 5 minutes and to at least 230° F., or for at least 7 minutes and to at least 220° F.

(11) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to insure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(b) *Equipment and procedures for pressure processing in water in still retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length or a temperature range of not more than 150° F. on a scale at least 9 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. Bulbs of indicating thermometers shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts this entry should be made in the side at the center, and the thermometer bulbs shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs shall extend directly into the water a minimum of at least 2 inches without a separable well or sleeve. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviate more than 1° F. from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each still retort adjusted to agree within 1° F. of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording thermometer bulb should be located adjacent to the bulb of the mercury-in-glass thermometer except in the case of a vertical retort equipped with a combination recorder-controller. In such vertical retorts the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement upon the control bulb.

(3) *Pressure gages.* (i) Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 lbs. or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(ii) An adjustable pressure relief, or control valve of a capacity sufficient to prevent undesired increase in retort pressure when the water valve is wide open and should be installed in the overflow line.

(4) *Steam introduction.* The distribution of steam in the bottom of the retort shall be accomplished in a manner adequate to provide uniform heat distribution throughout the retort. In vertical retorts, uniform steam distribution can be achieved by any of several methods. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(5) *Crate supports.* A bottom crate support shall be employed in vertical still retorts. Baffle plates shall not be used in the bottom of the retort. Centering guides should be installed so as to insure that there be about 1½-inches clearance between the side wall of the crate and the retort wall.

(6) *Stacking equipment.* Crates, trays, gondolas, etc., for holding containers shall be made of strap iron, adequately perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations should be approximately the equivalent of 1-inch holes on 2-inch centers. If divider plates are used between the layers of containers, they should be perforated as above.

(7) *Drain valve.* A nonclogging, watertight valve shall be used. Screens should be installed over all drain openings.

(8) *Water level indicator.* There shall be a means of determining the water level in the retort during operation (e.g., by using a gage water glass or petcock(s)). Water shall cover the top layer of containers during the entire coming-up-time and processing periods and should cover the top layer of containers during the cooling periods.

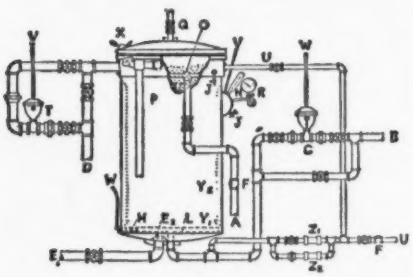
(9) *Air supply and controls.* In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be contolled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system. Air or water circulation shall be maintained continuously during the coming-up-time, processing, and cooling periods; if air is used to promote circulation it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

(10) *Cooling water supply.* In vertical retorts the cooling water should be introduced at the top of the retort between the water and container levels; in horizontal retorts the cooling water should be introduced into the suction side of the pump. A check valve should be included in the cooling water line.

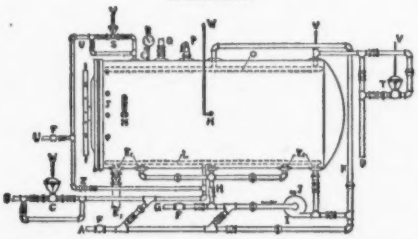
(11) *Retort headspace.* The headspace necessary to control the air pressure should be maintained between the water level and the top of the retort shell.

(12) *Vertical and horizontal still retorts.* Vertical and horizontal still retorts should follow the arrangements in the following diagrams or be equivalent.

Vertical Retorts



Horizontal Retorts



LEGEND FOR VERTICAL AND HORIZONTAL STILL RETORTS

A—Water line.
B—Steam line.
C—Temperature control.
D—Overflow line.
E_1—Drain line.
E_2—Screens.
F—Check valves.
G—Line from hot water storage.
H—Suction line and manifold.
I—Circulating pump.
J—Petcocks.
K—Recirculating line.
L—Steam distributor.
M—Temperature controller bulb.
N—Thermometer.
O—Water spreader.
P—Safety valve.
Q—Vent valve for steam processing.
R—Pressure gage.
S—Inlet air control.
T—Pressure control.
U—Air line.
V—To pressure control instrument.
W—To temperature control instrument.
X—Wing nuts.
Y_1—Crate support.
Y_2—Crate guides.
Z—Constant flow orifice valve.
Z_1—Constant flow orifice valve used during come-up.
Z_2—Constant flow orifice valve used during cook.

(13) *Water circulation.* When a water circulating system is used for heat distribution it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and should have an aggregate area not greater than the cross section area of the outlet line from the pump. The suction outlets should be protected with nonclogging screens to keep debris from entering the circulating system. The pump shall be equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations.

(14) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to insure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(c) *Equipment and procedures for pressure processing in steam in continuous agitating retorts.*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to insure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F. from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F. of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be ⅛-inch or larger and shall be wide open during the entire process, including the coming-up time. Bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top of the retort. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal.* Vents shall be located in that portion of the retort opposite the steam inlet. Air shall be removed before processing is started. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision shall be made for continuing drainage of condensate during the retort operation. The condensate bleeder in the bottom of the shell serves as an indicator of continuous condensate removal.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The speed shall be adjusted and recorded when the retort is started, at any time a speed change is made, and at intervals of sufficient frequency to insure that the retort speed is maintained as specified in the scheduled process. These adjustments and recordings should be made every 4 hours or less. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Emergency stops.* If a retort jams or breaks down during processing operations, necessitating cooling the retort for repairs, the retort shall either be operated as a still retort, with all containers being given a full still retort process before the retort is cooled, or the retort shall be cooled promptly and all containers shall be either reprocessed, repacked and reprocessed, or discarded.

(i) Any containers in the retort intake valve of a continuous retort at the time of breakdown shall either be reprocessed, repacked and reprocessed, or discarded.

(ii) Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of prompt cooling is followed, the subsequent handling methods used for the containers in the retort

at the time of stopping and cooling shall be entered on the production records.

(9) *Temperature drop.* If the temperature of the continuous retort drops below the temperature specified in the scheduled process while containers are in the retort, the retort reel shall be stopped promptly. An automatic device should be used to stop the reel when the temperature drops below the specified process temperature. Before the reel is restarted, all containers in the retort shall be given a complete still retort process if the temperature drop was 10° F. or more below the specified temperature. Alternatively, container entry to the retort shall be stopped and the reel shall be restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or discarded. Both the time at which the reel stopped and the time the retort was used for a still retort process, if so used, shall be marked on the recording chart and entered on the other production records required in this chapter. If the alternative procedure of emptying the retort is followed, the subsequent handling methods used for the containers in the retort at the time of the temperature drop shall be entered on the production records. If the temperature drop was less than 10° F., an authorized emergency still process approved by a qualified person(s) having expert knowledge of thermal processing requirements may be used before restarting the retort reel. Alternatively, container entry to the retort shall be stopped and an authorized emergency agitating process may be used before container entry to the retort is restarted. If any emergency process and procedure is utilized, no containers shall enter the retort during this time and the process and procedures used shall be entered on the production records.

(10) *Critical factors.* The minimum headspace of containers, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to insure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to insure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to insure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(d) *Equipment and procedures for pressure processing in steam in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to insure their accuracy. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch diameter opening, and shall be equipped with a 1/16-inch or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeder for external wells shall emit steam continuously during the entire processing period. Thermometers shall be installed where they can be accurately and easily read. A thermometer with a divided mercury column or that deviates more than 1° F. from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F. of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature recorder bulb well shall have a 1/16-inch or larger bleeder opening emitting steam continuously during the processing period.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Bleeders.* Bleeders, except those for thermometer wells, shall be ⅛ inch or larger and shall be wide open during the entire process, including the coming-up-time. Bleeders shall be located within approximately 1 foot of each end; additional bleeders shall be located not more than 8 feet apart along the top of the retort. In retorts having top steam inlet and bottom venting, a bleeder shall be installed in the bottom of the retort to ensure removal of condensate. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Venting and condensate removal.* The air in each retort shall be removed before processing is started. At the time steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation.

(7) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to ensure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on retorts shall be provided.

(8) *Critical factors.* The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to insure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process, the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to insure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to insure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(e) *Equipment and procedures for pressure processing in water in discontinuous agitating retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length. The scale division shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to insure their accuracy. Bulbs of indicating thermometers shall be installed either

within the retort shell or in external wells attached to the retort. Thermometers shall be installed where they can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F. from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F. of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the retort shell or in a well attached to the shell.

(3) *Pressure gages.* Each retort shall be equipped with a pressure gage. The gage should be graduated in divisions of 2 pounds or less, should be connected to the retort shell or external well by a short gooseneck tube, and should be not more than 4 inches higher than the gooseneck. The gage should be checked for accuracy at least once a year.

(4) *Steam controller.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

(5) *Retort speed timing.* The rotational speed of the retort shall be specified in the scheduled process. The rotational speed shall be adjusted, as necessary, to insure that the speed is as specified in the scheduled process. The rotational speed as well as the process time shall be recorded for each retort load processed. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes shall be provided.

(6) *Air supply and controls.* Means shall be provided for introducing compressed air at the proper pressure and rate. The proper pressure shall be controlled by an automatic pressure control unit. A check valve shall be provided in the air supply line to prevent water from entering the system.

(7) *Critical factors.* The minimum headspace of containers in each retort load to be processed, if specified in the scheduled process, shall be measured and recorded at intervals of sufficient frequency to insure that the headspace is as specified in the scheduled process. The headspace of solder-tipped, lap seam (vent hole) cans may be measured by net weight determinations. Where the product consistency is specified in the scheduled process the consistency of the product shall be determined by objective measurements on the product taken from the filler before processing and recorded at intervals of sufficient frequency to insure that the consistency is as specified in the scheduled process. Minimum closing machine vacuum (in vacuum-packed products), maximum drained weight, minimum net weight, and percent solids shall be as specified in the scheduled process for all products where deviations from such specifications may affect the scheduled process. Measurements of these critical factors shall be made and recorded at intervals of sufficient frequency to insure that they are as specified in the scheduled process. All measurements and recordings of critical factors should be made at intervals not to exceed 15 minutes.

(f) *Equipment and procedures for pressure processing in steam in hydrostatic retorts*—(1) *Indicating mercury-in-glass thermometer.* Each retort shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length. The scale divisions shall be no more than 2° F. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to insure their accuracy. The thermometer shall be located in the steam dome near the steam-water interface. Where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, a mercury-in-glass thermometer shall be located in each hydrostatic water leg in a position near the bottom automatic recorder so that it can be accurately and easily read. A thermometer that has a divided mercury column or that deviates more than 1° F. from the standard shall be repaired or replaced. The mercury thermometer—not the recorder chart—shall be the reference instrument for indicating the processing temperature.

(2) *Temperature recording device.* There shall be an accurate temperature recording device for each retort adjusted to agree within 1° F. of the known accurate mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The chart graduations shall not exceed 2° F. within a range of 10° F. of the processing temperature. Each chart shall have a working scale of not more than 50° F. per in. within a range of 20° F. of the processing temperature. This recorder may be combined with the steam controller and may be a recording-controlling instrument. The temperature recorder bulb shall be installed either within the steam dome or in a well attached to the dome. Temperature recorder bulb wells shall have a $\frac{1}{16}$-inch or larger bleeder opening emitting steam continuously during the entire processing period. Additional temperature recorder bulbs shall be installed in the hydrostatic water legs if the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs.

(3) *Recording of temperatures.* Temperatures indicated by the mercury-in-glass thermometer or thermometers shall be entered on a suitable form during processing operations. Temperatures shall be recorded by an accurate automatic recorder or recorders at the following points:

(i) In the steam chamber between the steam-water interface and the lowest container position.

(ii) Near the top and the bottom of each hydrostatic water leg if the scheduled process specifies maintenance of particular temperatures in the legs.

(4) *Venting.* Before the start of processing operations, the retort steam chamber or chambers shall be vented to ensure removal of air.

(5) *Bleeders.* Bleeder openings $\frac{1}{4}$-inch or larger shall be located at the end of the steam chamber or chambers opposite from the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the coming-up-time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(6) *Retort speed.* The speed of the container conveyor chain shall be specified in the scheduled process and shall be determined and recorded at the start of processing and at intervals of sufficient frequency to insure that the retort speed is maintained as specified. The speed should be determined and recorded every 4 hours. An automatic device should be used to stop the chain when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(7) *Critical factors.* (i) Where maximum drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

(ii) Minimum closing machine vacuum (in vacuum-packed products) shall be observed and recorded at intervals of sufficient frequency to ensure that the vacuum is as specified in the scheduled process.

(iii) Such measurements and recordings should be made at intervals not to exceed 15 minutes.

(g) *Aseptic processing and packaging systems*—(1) *Product sterilizer*—(i) *Equipment*—(a) *Temperature indicating device.* Each product sterilizer shall be equipped with at least one mercury-in-glass thermometer that has a temperature range of not more than 100° F. in the processing range on a scale at least 7 inches in length, or an equivalent temperature indicating device, such as a thermocouple-recorder. The scale divisions or chart graduations of the temperature indicating device shall be no more than 2° F. within the range of 10° F. of the product sterilization operating range. The device shall be installed in the product at the holding tube outlet between the holding tube and the inlet

to the cooler. The temperature indicating device shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently as may be necessary to ensure its accuracy. The device shall be installed so that it can be accurately and easily read. A thermometer that has a divided mercury column or a device that deviates more than 1° F. from the standard shall be repaired or replaced. The temperature indicating device shall be the reference instrument for indicating the processing temperature.

(b) *Temperature recording device.* There shall be an accurate temperature recording device on each product presterilizer. The temperature sensor shall be located in the presterilized product at the holding tube outlet between the holding tube and the inlet of the cooler. The recording device shall be adjusted to agree with a known accurate standard mercury-in-glass thermometer. A means of preventing unauthorized changes in adjustment shall be provided. The recording device shall not deviate more than 1° F. from the standard thermometer; it shall be installed so that it can be accurately and easily read. The recording chart graduations shall not exceed 2° F. within a range of 10° F. of the desired product sterilization temperature. The chart shall have a working scale of not more than 50° F. per inch within a range of 20° F. of the processing temperature.

(c) *Temperature recorder-controller.* An accurate temperature recorder-controller shall be located in the product sterilizer at the final heater outlet. It shall be capable of assuring that the desired product sterilization temperature is maintained. The chart graduations shall not exceed 2° F. within a range of 10° F. of the desired product sterilization temperature.

(d) *Product-to-product regenerators.* Where a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator to insure that any leakage in the regenerator will be from the sterilized product into the unsterilized product.

(e) *Differential pressure recorder-controller.* Where a product-to-product regenerator is used, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 2 pounds per square inch on a working scale of not more than 20 pounds per square inch per inch. The controller shall be tested for accuracy against a known accurate standard pressure indicator, upon installation and at least once every 3 months of operation thereafter or more frequently as may be necessary to ensure its accuracy. One pressure sensor shall be installed at the sterilized product regenerator outlet, and the other pressure sensor shall be installed at the unsterilized product regenerator inlet.

(f) *Metering pump.* A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed changes shall be provided.

(g) *Product holding tube.* The product sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion between the product inlet and the product outlet can be heated, and it shall be sloped upward at least 0.25 inch per foot.

(ii) *Operation—(a) Startup.* Prior to the start of aseptic processing operations, the product sterilizer shall be brought to a condition of commercial sterility.

(b) *Temperature drop in product sterilizing holding tube.* When product temperature in the holding tube drops below the temperature specified in the scheduled process, the product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before flow is resumed to the filler.

(c) *Loss of proper pressures in the regenerator.* Where a regenerator is used the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 1 lb. per square in. greater than the pressure of unsterilized product in the regenerator. Product flow to the filler shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

(d) *Records.* Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process: Temperature indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder-controller at final heater outlet; differential pressure recorder-controller, if a product-to-product regenerator is used; and product flow rate as established by the metering pump or as determined by filling and closing rates. Such measurements and recordings should be made at intervals not to exceed 1 hr.

(2) *Container sterilizing, filling, and closing operation—*(i) *Equipment—(a) Recording device.* The container and closure sterilization system and product filling and closing system shall be instrumented to show that commercial sterility is being achieved. Automatic recording devices shall be used to record, where applicable, the sterilization media flow rates and/or temperatures. Where a batch system is used for container sterilization, the sterilization conditions shall be recorded.

(b) *Timing method(s).* A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment as specified in the scheduled process, or to control the sterilization cycle at the rate as specified in the scheduled process. A means of preventing unauthorized speed changes shall be provided.

(ii) *Operation—(a) Startup.* Prior to the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

(b) *Loss of sterility.* In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

(c) *Records.* Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved; such measurements shall include the sterilization media flow rates and/or temperatures, the container and closure rates (if applicable) through the sterilizing system, and the sterilization conditions if a batch system is used for container sterilization. The measurements and recordings should be made at intervals not to exceed 1 hour.

(3) *Incubation.* Incubation tests shall be conducted on a representative sample of containers of product from each code; records of the tests shall be maintained.

(h) *Equipment and procedures for flame sterilizers.* The container conveyor speed shall be specified in the scheduled process. The container conveyor speed shall be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Such measurements and recordings should be done at 1-hour intervals. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. A means of preventing unauthorized speed changes on the conveyor shall be provided. The surface temperature of at least one container from each conveyor channel shall be measured and recorded at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained. Such measurements and recordings should be done at intervals not to exceed 15 minutes.

(i) *New systems.* The development of new systems for the thermal processing of low-acid foods in hermetically sealed containers shall conform to the applicable requirements of this part and shall ensure that the methods and controls used for the manufacture, processing, and/or packing of such foods are operated or administered in a manner adequate to achieve commercial sterility.

§ 128b.7 Containers.

(a) *Closures.* Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded, and corrective action shall be taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure su-

pervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used, and shall record his observations. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closure machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. Where irregularities are found, the corrective action shall be recorded.

(1) Teardown examinations for double seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

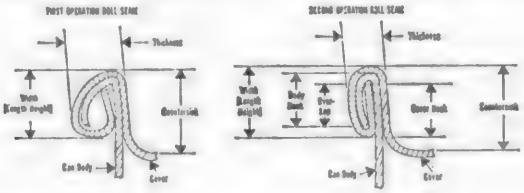
(*a*) Micrometer measurement system:

Required	*Optional*
Cover hook.	Overlap (by calculation).
Body hook.	Countersink.
Width (length, height).	Thickness.
Tightness (observation for wrinkle).	

(*b*) Seam scope or projector:

Required	*Optional*
Body hook.	Width (length, height).
Overlap.	Cover hook.
Tightness (observation for wrinkle).	Countersink.
	Thickness.

(*c*) Can double seam terminology:



(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

The theoretical overlap length=
CH+BH+T−W where
CH=cover hook
BH=body hook
T=cover thickness, and
W=seam width (height, length)

(2) For closures other than double seams, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to insure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) *Cooling.* Container cooling water should be chlorinated as necessary by the processor so that there is a measurable free chlorine residual at the water discharge point of the container cooler. Other safe chemical or physical treatment which is equivalent to chlorination in its bactericidal effect may be used. Where pressure cooling is utilized, adequate pressure should be maintained for a time sufficient to prevent permanent distortion of the container.

(c) *Coding.* Each hermetically sealed container of low-acid processed food shall be marked with an identifying code which shall be permanently visible to the naked eye. Where the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, provided that the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: Intervals of every 4 to 5 hours; personnel shift changes; or batches, provided the containers comprising such batch do not extend over a period of more than one personnel shift.

(d) *Postprocess handling:* Where cans are handled on belt conveyors, such conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts which come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated in such a manner as to preserve the can seam or other container closure integrity.

§ 128b.8 Processing and production records.

(a) Processing and production information shall be entered by the retort or processing system operator, or other designated person, on forms which shall include the product, the code number, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the minimum initial temperature, the actual processing time and temperature, the mercury-in-glass and recording thermometer readings, and other appropriate processing data. Closing machine vacuum (in vacuum-packed products), maximum drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and/or temperature to which vented (as applicable).

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, where specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, where the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature indicating device and the temperature recorder; product temperature in the final heater outlet as indicated by the temperature recorder-controller; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the metering pump or by filling and closing rates; sterilization media flow rate and/or temperature; retention time of containers, and closures where applicable, in the sterilizing environment; and, where a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the end of the holding period; nature of container.

(b) Recording thermometer charts shall be identified by date, and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on the record shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and the retort or processing system operator or such designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and prior to shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and produc-

tion records for completeness and to insure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed by the person conducting the review.

(c) Written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and shall be reviewed by management with sufficient frequency to assure that the containers are hermetically sealed.

(d) Copies of all records provided for in this part except those required under § 128b.4 establishing scheduled processes, shall be maintained at the processing plant for a period of not less than 3 years.

§ 128b.9 Deviations in processing.

Whenever any process is less than the scheduled process for any low-acid food or container system as disclosed from records, by processor check, or otherwise, the commercial processor of such low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, shall set aside that portion of the production involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless such evaluation demonstrates that the product had been given a thermal process that rendered it free of micro-organisms of potential public health significance, the product set aside either shall be fully reprocessed to render it commercially sterile or it shall be destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the production involved may be shipped in normal distribution. Otherwise, the portion of the production involved shall be destroyed.

§ 128b.10 Personnel.

All operators of retorts, processing systems, and aseptic processing and packaging systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections, and has been identified by that school as having satisfactorily completed the prescribed course of instruction.

Effective date. This order shall become effective March 26, 1973, except as to those provisions of § 128b.6 regarding the installation of recording thermometers on thermal processing equipment and the provisions of § 128b.10, which concerns the training of personnel. Those provisions of § 128b.6 regarding the installation of recording thermometers on thermal processing equipment shall become effective June 25, 1973. The provisions of § 128b.10, which concerns the training of personnel, shall become effective September 25, 1974.

(Secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055, 21 U.S.C. 342(a)(4), 371(a))

Dated: January 12, 1973.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.73-1167 Filed 1-23-73;11:51 am]

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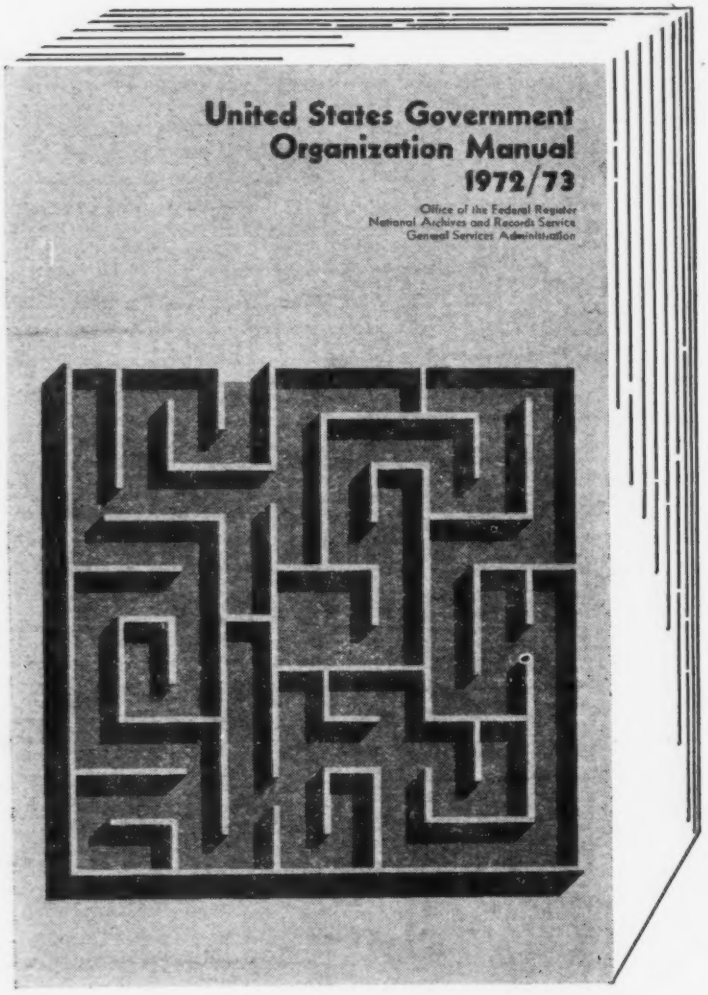

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